

Atty. Docket No.: 3284/1235

RECEIVED
PATENT
SEP 26 2003
TECH CENTER 1800/2900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Habener, et al.
Serial No.: 09/963,875
Filed: September 26, 2001
Titled: STEM CELLS OF THE ISLETS OF
LANGERHANS AND THEIR USE IN
TREATING DIABETES MELLITUS

Examiner: M.A. Belyavsky
Group Art Unit: 1644
Conf. No.: 9674

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8a

I hereby certify that this correspondence (and any paper or fee referred to as being enclosed) is being deposited with the United States Postal Service as First Class Mail on the date indicated below in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Kathleen M. Williams

Name of Person Mailing

Signature of Person Mailing Paper

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir:

This Response is being filed in response to the Office Action dated July 2, 2003.

Attached is a Petition for Extension of Time under 37 C.F.R. §1.136(a) to extend the period of response two months, up to, and including October 2, 2003, along with the necessary fee. Please charge any additional fees required in connection with the papers transmitted herewith to Deposit Account No. 16-0085, Reference No. 3284/1235.

Applicants wish to thank Examiner Belyavskyi for the courtesy extended to their attorneys during a telephonic interview on September 3, 2003. Applicants believe the interview was helpful and productive, the essence of which is summarized below.

Applicants have filed herewith a preliminary amendment wherein claim 43 has been amended to claim "The isolated stem cell of claim 39 or 41 that differentiates to form at least one of: insulin-producing beta cells, glucagon-producing alpha cells; pseudo-islet like aggregates; and hepatocytes."

As discussed in the telephonic interview of September 3, 2003, claims 39-47 all relate to an isolated, nestin-positive human pancreatic or liver stem cell. Depending on the culture conditions, the isolated stem cell can differentiate to at least one of insulin-producing beta cells, glucagon-producing alpha cells; pseudo-islet like aggregates; and hepatocytes. Claims 43-46, as filed, therefore, do not claim patentably distinct products but rather claim the isolated stem cell of claim 39, wherein the cell has been further limited to a cell that has the additional property of

Atty Docket No.: 3284/1235 (Serial No.: 09/963,875)

Inventors: Habener, et al.

Filed: September 26, 2001

Response to Restriction Requirement

Page 2

differentiating to insulin-producing beta cells, glucagon-producing alpha cells; pseudo-islet like aggregates; or hepatocytes.

Claim 47 claims "[t]he isolated stem cell of claim 39 or 41 that does not express class I MHC antigens.". The subject matter of claim 47 is not patentably distinct from the subject matter of claims 43-46 as filed. Claim 47, like claim 40 which adds the limitation "wherein said cell is also GLP-1R positive", claims the isolated stem cell of claim 39, wherein the cell has been further limited to a cell that does not express class I MHC antigens.

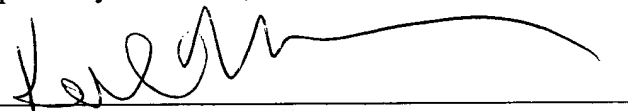
By examining claims 39-47 and 74 as a single group no undue burden is placed on the Examiner since these claims all relate to the same invention: "an isolated, nestin-positive human pancreatic or liver stem cell." In contrast, an undue burden would be placed on Applicant if further prosecution of the subject matter of these ten claims requires prosecution of five separate applications.

In view of the above amendment, Applicants respectfully elect **Group VI, Claims 39-42** (original), claim 43 (currently amended) and claim 74 (original) for prosecution on the merits, with traverse.

In response to the Examiner's telephonic request for a species election, Applicants elect the species "insulin producing beta cells."

Respectfully submitted,

Date: 9/18/03



Name: Kathleen M. Williams
Registration No.: 34,380
Customer No.: 29933
Palmer & Dodge LLP
111 Huntington Avenue
Boston, MA 02199-7613
Tel: 617-239-0100